

## REMARKS

### Oath/Declaration

A new Declaration executed by co-inventor Kuo is submitted herewith. The new Declaration complies with 37 CFR §1.67(a) and §1.52(c).

### Drawings

Corrected drawings are submitted herewith. The corrected drawings comply with 37 CFR §1.185(a). No new matter has been added.

### Amendments to the Specification

The specification has been amended to insert the related application data. No new matter has been added.

The specification has been further amended to reflect the proprietary nature of the trademarks contained within the specification. No new matter has been added.

The Brief Description of the Drawings has been amended regarding Figures 1 and 16 to agree with the figure legends of the formal drawings filed herewith. No new matter has been added.

### Amendments to the Claims

Claims 4-9, 14-20, and 24-48 have been canceled.

Independent claim 1 has been amended to specify that the isolated peptide "consists of" a particular amino acid sequence. Support for the amendment to claim 1 can be found throughout the specification. The amendment to claim 1, and dependent claims thereof, are fully supported by the specification as originally filed. Therefore, Applicants are entitled to the priority date of the parent applications.

Claims 2, 3, 10-13, and 22 have been amended to provide proper dependency.

The foregoing claim amendments should in no way be construed as an acquiescence to any of the Examiner's rejections, and have been made solely to expedite prosecution of the present application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application. No new matter has been added to this application.

***Rejection of Claims 1-6, 9-15, 21-23, 26-28, and 38-41***

***Under Obviousness-type Double Patenting***

Claims 1-6, 9-15, 21-23, 26-28, and 38-41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,710,126. Applicants respectfully submit that a terminal disclaimer will be filed upon the indication of allowable subject matter, if appropriate.

***Rejection of Claims 1-6, 9-15, 21, 23, 26-28, and 38-41***

***Under 35 U.S.C. §112, First Paragraph***

Claims 1-6, 9-15, 21, 23, 26-28, and 38-41 are rejected under 35 U.S.C. §112, first paragraph, "as failing to comply with the written description requirement." Specifically, the Examiner states that claims 1 and 2

appear to encompass fragments of the peptides recited in the claims wherein the fragment contains a T cell epitope . . . There is no disclosure in the specification of T cell epitopes for the peptides recited in the claims that are smaller than the size of the actual peptides (e.g., 16 or 20 amino acids) . . . Similarly, there is no disclosure in the specification of peptides other than the full length peptides recited in the claims which might have the properties recited in claims 3-6 . . . Regarding claims 10-15, there is no disclosure in the specification of peptide with said functional properties other than the specific peptides recited in claim 1. Regarding claims 26 and 40, there is no written description in the specification of any composition which has been shown to have the functional properties recited in said claim.

From this, the Examiner concludes that "the written description provided in the specification is not commensurate with the scope of the claimed inventions."

First, Applicants note that claims 4-6, 9, 14, and 15 have been canceled. Therefore, this rejection is moot as it pertains to claims 4-6, 9, 14, and 15.

With regard to the remaining claims, Applicants respectfully traverse this rejection. However, to expedite prosecution, the claims have been amended to specify the full length peptides recited in the claims. Accordingly, this rejection is now moot.

***Rejection of Claims 21-23 and 26 Under 35 U.S.C. §112, First Paragraph***

Claims 21-23 and 26 are rejected under 35 U.S.C. §112, first paragraph, "as failing to comply with the enablement requirement." Specifically, the Examiner states that

[t]he specification does not disclose how to use the instant invention for the treatment of disease in vivo in humans . . . There is no in vitro or in vivo data of

any kind demonstrating that the claimed peptides can be used in vivo for the treatment of human disease. The state of the art is unpredictable in the absence of any in vitro or in vivo data (as per the specification) as to whether the method of the instant invention can be used for the treatment of human disease.

The Examiner concludes that "undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification.

Claim 26 has been canceled. Therefore, this rejection is moot as it pertains to claim 26.

With regard to claims 21-23, Applicants respectfully traverse this rejection.

Claims 21 and 23 are not drawn to methods of treating diseases in human. Instead, claims 21-23 are drawn to compositions comprising specific *Lol p V* peptides. Such compositions, as taught by Applicants, are "useful in allergy diagnosis and/or useful in allergy therapy . . ." (see, for example, page 16, lines 19-24). The claimed compositions are not limited to a therapeutic use, but also can be used in allergy diagnosis. Accordingly, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.

As admitted by the Examiner, several of the claimed peptides stimulate T cell proliferation, *i.e.*, have T cell stimulating activity, such as induction of T cell proliferation, lymphokine secretion and/or T cell anergy/tolerization. Therefore such peptides having human T cell stimulating activity can also be used, for example, in methods of determining in individuals the presence of immunoglobulin specific for a protein allergen, *e.g.*, ryegrass protein allergen, and the ability of T cells of the individuals to be stimulated by T cell epitope(s) of the protein antigen. If T cell stimulation occurs, the claimed compositions could also be used in methods of treatment.

Based on at least the foregoing, the application is enabling for the claimed compositions.

***Rejection of Claims 1-6, 9, 11-15, 21-23, and 26-28***

***Under 35 U.S.C. §112, Second Paragraph***

Claims 1-6, 9, 11-15, 21-23, and 26-28 are rejected under 35 U.S.C. §112, second paragraph, "as being indefinite." In particular, the Examiner states that "the peptides recited in the claims (as small as 7 amino acids) are shorter than the size of the peptides actually recited in the claims."

Claims 4, 5, 9, 14, 15, and 20 have been canceled. Therefore, this rejection is moot as it pertains to claims 4, 5, 9, 14, 15, and 20. With respect to the remaining claims, Applicants

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respectfully traverse this rejection. However, to expedite prosecution, the claims have been amended to specify the full-length peptides recited in the claims. Therefore, the claims are clear and definite.

***Rejection of Claims 1-6, 9, 12-15, 21-23, and 26-28 Under 35 U.S.C. §102(b)***

Claims 1-6, 9, 12-15, 21-23, and 26-28 are rejected under 35 U.S.C. §102(b) "as anticipated by Griffith *et al.* (WO 95/06728)." Applicants respectfully traverse this rejection.

As explained above in regard to the amendments to the claims (see Remarks section), the present application is entitled to the priority dates of the parent applications. Accordingly, Griffith *et al.* (WO 95/06728) is not an appropriate prior art document.

***Rejection of Claims 1, 3-5, 12-15, 21, 23, 26-28, and 38-41 Under 35 U.S.C. §102(b)***

Claims 1-6, 9, 12-15, 21-23, 26-28, and 38-41 are rejected under 35 U.S.C. §102(b) "as anticipated by Singh *et al.* (US Patent 5,721,119)." Applicants respectfully traverse this rejection.

Singh *et al.* issued on February 24, 1998. The filing date of the instant application (not taking into account the priority claim of the instant application) is November 20, 1996. Accordingly, Singh *et al.* was not patented more than one year prior to the date of the instant application, let alone prior to the filing date of its parent applications. Therefore, Singh *et al.* is not an appropriate prior art document under 35 U.S.C. §102(b).

***Rejection of Claims 1-6, 9-15, 21-23, 26-28, and 38-41 Under 35 U.S.C. §103(a)***

Claims 1-6, 9-15, 21-23, 26-28, and 38-41 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Singh *et al.* in view of Perez *et al.*" Applicants respectfully traverse this rejection. However, to expedite prosecution, the claims have been amended to specify that the isolated peptides "consist of" particular amino acid sequences. The particular amino acid sequences are not taught or suggested in the cited references. Therefore, the claims are patentable.

**CONCLUSION**

Based on the foregoing, all the claims are in condition for allowance. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

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Respectfully submitted,

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